



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2011-1020; FRL-9346-3]

### **Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) transmitted its 69<sup>th</sup> Report to the EPA Administrator on April 5, 2012. In the 69<sup>th</sup> ITC Report, which is included with this notice, the ITC is adding a category of cadmium compounds including any chemical that contains cadmium as part of that chemical's structure, 6 non-phthalate plasticizers, 25 phosphate ester flame retardants, 2 other flame retardants, 9 chemicals to which children living near hazardous waste sites may be exposed, and a category of 69 diisocyanates and related compounds (including 14 Action Plan chemicals and 55 related compounds) to the TSCA *Priority Testing List*. In addition, the ITC is removing 103 cadmium compounds and 14 High Production Volume (HPV) Challenge Program orphan chemicals from the *Priority Testing List* during this reporting period (June to November 2011). The ITC is adding the category of cadmium compounds and removing 103 cadmium compounds to provide a more comprehensive approach to assessing cadmium compounds' safety.

**DATES:** Comments must be received on or before [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-1020, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2011-1020. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions*: Direct your comments to docket ID number EPA-HQ-OPPT-2011-1020. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA

recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:*

Dr. John D. Walker, Interagency Testing Committee (7401M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave.,

NW., Washington, DC 20460-0001; telephone number: (202) 564-7527; fax number: (202) 564-7528; email address: *walker.johnd@epa.gov*.

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

This notice is directed to the public in general. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process TSCA-covered chemicals and you may be identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this notice is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment

that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

- iv. Describe any assumptions and provide any technical information and/or data that you used.

- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

- vi. Provide specific examples to illustrate your concerns and suggest alternatives.

- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

- viii. Make sure to submit your comments by the comment period deadline identified.

## **II. Background**

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) authorizes the EPA Administrator to promulgate regulations under TSCA section 4(a) requiring testing

of chemicals and chemical groups in order to develop data relevant to determining the risks that such chemicals and chemical groups may present to health or the environment. Section 4(e) of TSCA established the ITC to recommend chemicals and chemical groups to the EPA Administrator for priority testing consideration. Section 4(e) of TSCA directs the ITC to revise the TSCA section 4(e) *Priority Testing List* at least every 6 months.

You may access additional information about the ITC at

<http://www.epa.gov/opptintr/itc>.

#### *A. The 69<sup>th</sup> ITC Report*

The ITC is adding a category of cadmium compounds including any chemical that contains cadmium as part of that chemical's structure, 6 non-phthalate plasticizers, 25 phosphate ester flame retardants, 2 other flame retardants, 9 chemicals to which children living near hazardous waste sites may be exposed, and a category of 69 diisocyanates and related compounds (including 14 Action Plan chemicals and 55 related compounds) to the TSCA section 4(e) *Priority Testing List*. In addition, the ITC is removing 103 cadmium compounds and 14 HPV Challenge Program orphan chemicals from the *Priority Testing List* during this reporting period (June to November 2011). The ITC is adding the category of cadmium compounds and removing 103 cadmium compounds to provide a more comprehensive approach to assessing cadmium compounds' safety.

#### *B. Status of the Priority Testing List*

The *Priority Testing List* includes 2 alkylphenols, 16 chemicals with insufficient dermal absorption rate data, and 164 HPV Challenge Program orphan chemicals, a category of cadmium compounds including any chemical that contains cadmium as part of that chemical's structure, 6 non-phthalate plasticizers, 25 phosphate ester flame

retardants, 2 other flame retardants, 9 chemicals to which children living near hazardous waste sites may be exposed, and a category of 69 diisocyanates and related compounds (including 14 Action Plan chemicals and 55 related compounds).

**List of Subjects**

Environmental protection, Chemicals, Hazardous substances.

Dated: May 15, 2012.

Wendy C. Hamnett,

*Director, Office of Pollution Prevention and Toxics.*



## **Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency**

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#### **Summary**

The ITC is adding a category of cadmium compounds including any chemical that contains cadmium as part of that chemical's structure, 6 non-phthalate plasticizers, 25 phosphate ester flame retardants, 2 other flame retardants, 9 chemicals to which children living near hazardous waste sites may be exposed, and a category of 69 diisocyanates and related compounds (including 14 Action Plan chemicals and 55 related compounds) to the Toxic Substances Control Act (TSCA) section 4(e) *Priority Testing List*. In addition, the ITC is also removing 103 cadmium compounds and 14 High Production Volume (HPV) Challenge Program orphan chemicals from the *Priority Testing List* during this reporting period (June to November 2011). The ITC is adding the category of cadmium

compounds and removing 103 cadmium compounds to provide a more comprehensive approach to assessing cadmium compounds' safety.

The TSCA section 4(e) *Priority Testing List* is Table 1 of this unit.

**TABLE 1.--TSCA SECTION 4(E) PRIORITY TESTING LIST (NOVEMBER 2011)**

<b>ITC Report</b>	<b>Date</b>	<b>Chemical Name/Group</b>	<b>Action</b>
31	January 1993	2 Chemicals with insufficient dermal absorption rate data, methylcyclohexane and cyclopentane	Designated
32	May 1993	10 Chemicals with insufficient dermal absorption rate data	Designated
35	November 1994	4 Chemicals with insufficient dermal absorption rate data, cyclopentadiene, formamide, 1,2,3-trichloropropane and <i>m</i> -nitrotoluene	Designated
37	November 1995	Branched 4-nonylphenol (mixed isomers)	Recommended
41	November 1997	Phenol, 4-(1,1,3,3-tetramethylbutyl)-	Recommended
55	December 2004	161 High Production Volume (HPV) Challenge Program orphan chemicals	Recommended
56	August 2005	3 HPV Challenge Program orphan chemicals	Recommended
68	May 2011	Cadmium	Recommended
69	November 2011	Cadmium compounds	Recommended
69	November 2011	6 Non-phthalate plasticizers	Recommended
69	November 2011	25 Phosphate ester flame retardants	Recommended
69	November 2011	2 Other flame retardants	Recommended
69	November 2011	9 Chemicals to which children living near hazardous waste sites may be exposed	Recommended
69	November 2011	69 Diisocyanates and related compounds	Recommended

## **I. Background**

The ITC was established by TSCA section 4(e) “to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of rules for testing under section 4(a).... At least every six months ..., the Committee shall make such revisions to the *Priority Testing List* as it determines to be necessary and transmit them to the Administrator together with the Committee's reasons for the revisions” (Public Law 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*). ITC reports are available from [regulations.gov](http://www.regulations.gov) (<http://www.regulations.gov>) after publication in the **Federal Register**. The ITC produces its revisions to the *Priority Testing List* with administrative and technical support from the ITC staff, ITC members, and their U.S. Government organizations, and contract support provided by the Environmental Protection Agency (EPA). ITC members and staff are listed at the end of this report.

## **II. TSCA Section 8 Reporting**

### *A. TSCA Section 8 Reporting Rules*

Following receipt of the ITC's report (and the revised *Priority Testing List*) by the EPA Administrator, EPA's Office of Pollution Prevention and Toxics (OPPT) may add the chemicals from the revised *Priority Testing List* to the TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) rule (40 CFR part 712) and/or the TSCA section 8(d) Health and Safety Data Reporting (HaSDR) rule (40 CFR part 716). The PAIR rule requires manufacturers (including importers) of chemicals added to the *Priority Testing List* to submit to EPA certain production and exposure information (<http://www.epa.gov/oppt/chemtest/pubs/pairform.pdf>). As provided for in the PAIR rule, whenever EPA announces the receipt of an ITC report, EPA amends, unless otherwise

instructed by the ITC, the PAIR rule by adding the recommended (or designated) chemicals that have been added to the *Priority Testing List* by the ITC.

The HaSDR rule requires certain past, current, and proposed manufacturers, importers, and (if specified by EPA) processors of listed chemicals to submit to EPA copies and lists of unpublished health and safety studies on the listed chemicals that they manufacture, import, or (if specified by EPA) process. As provided for in the HaSDR rule, whenever EPA announces the receipt of an ITC report, EPA amends, unless otherwise instructed by the ITC, the HaSDR rule by adding the recommended (or designated) chemicals that have been added to the *Priority Testing List* by the ITC.

#### *B. ITC's Use of TSCA Section 8 and Other Information*

The ITC's use of TSCA section 8 and other information is described in the 52<sup>nd</sup> ITC Report (Ref. 1).

#### *C. New Request to Add Chemicals to the TSCA Section 8(d) HaSDR Rule*

The ITC is requesting that EPA add a category of cadmium compounds including any chemical that contains cadmium as part of that chemical's structure, 6 non-phthalate plasticizers, 25 phosphate ester flame retardants, 2 other flame retardants, 9 chemicals to which children living near hazardous waste sites may be exposed, and a category of 69 diisocyanates and related compounds to the TSCA section 8(d) HaSDR rule. The category of cadmium compounds, 6 non-phthalate plasticizers, 25 phosphate ester flame retardants, 2 other flame retardants, 9 chemicals to which children living near hazardous waste sites may be exposed, and a category of 69 diisocyanates and related compounds are discussed in section IV of this report.

### **III. ITC's Activities During this Reporting Period (June to November 2011)**

During this reporting period, the ITC discussed the need to expand the definition of the cadmium compounds beyond the 103 cadmium compounds recommended in the 68<sup>th</sup> ITC Report (Ref. 2). As a result the ITC is recommending a category of cadmium compounds including any chemical that contains cadmium as part of that chemical's structure and removing the 103 cadmium compounds from the *Priority Testing List*. The ITC is adding the category of cadmium compounds and removing 103 cadmium compounds to provide a more comprehensive approach to assessing cadmium compounds' safety.

In addition, the ITC discussed the use of TSCA section 8(d) to obtain biomonitoring data. As a result of these discussions, the ITC is adding 6 non-phthalate plasticizers, 25 phosphate ester flame retardants, 2 other flame retardants, and 9 chemicals to which children living near hazardous waste sites may be exposed to the *Priority Testing List* and asking EPA to add these chemicals to the TSCA section 8(d) HaSDR rule to obtain biomonitoring data. The ITC also discussed adding a category of 69 diisocyanates and related compounds to the *Priority Testing List* and to the TSCA section 8(d) HaSDR rule to facilitate EPA's ability to obtain existing studies. Finally, the ITC discussed EPA's Notice of Proposed Rulemaking (NPRM) for HPV Challenge Program chemicals (Ref. 3). As a result of these discussions the ITC is removing 14 HPV Challenge Program orphan chemicals from the *Priority Testing List*.

#### **IV. Revisions to the TSCA Section 4(e) *Priority Testing List***

##### *A. Chemicals Added to the Priority Testing List*

1. *Cadmium compounds--i. Recommendation.* The EPA and the Consumer Product Safety Commission (CPSC) request that the ITC add the category cadmium compounds

to the *Priority Testing List* to obtain health and safety studies on cadmium compounds that are present in any consumer product. The cadmium compounds category includes any chemical that contains cadmium as part of that chemical's structure.

ii. *Rationale for recommendation.* The EPA and the CPSC are concerned with the content of cadmium and cadmium compounds in certain children's toys, jewelry, and other consumer products due to known toxicity and health concerns from exposure to cadmium and cadmium compounds. The EPA has expanded the cadmium compounds category to include any chemical that contains cadmium as part of that chemical's structure to capture information on more than the 103 cadmium compounds listed in the 68<sup>th</sup> ITC Report (Ref. 2). Cadmium remains on the *Priority Testing List* as recommended in the 68<sup>th</sup> ITC Report.

iii. *Supporting information.* The supporting information for cadmium and cadmium compounds is described in the 68<sup>th</sup> ITC Report. However, the supporting information for this report is for cadmium and cadmium compounds, not cadmium or cadmium compounds.

iv. *Information needs.* EPA and CPSC need health and safety studies for assessing the extent and degree of exposure and potential hazard associated with cadmium and cadmium compounds including: Epidemiological or clinical studies; occupational exposure, health effects, and ecological effects studies; and environmental fate studies (including relevant physical chemical properties).

For example, EPA and CPSC need studies about the total amount of cadmium and cadmium compounds contained in a product, the solubility, and bioavailability of cadmium and cadmium compounds (including accessibility of cadmium and cadmium

compounds to children and studies of the age and foreseeable behavior of children exposed to a product for children and/or children's toys), the foreseeable duration and route of potential cadmium and cadmium compounds exposure through contact with products, and studies on the marketing, patterns of use, and lifecycle of cadmium-containing products.

2. *Non-phthalate plasticizers, phosphate ester flame retardants, and other flame retardants--i. Recommendation.* The CPSC requests that the ITC add 6 non-phthalate plasticizers, 25 phosphate ester flame retardants, and 2 other flame retardants to the *Priority Testing List* to obtain biomonitoring studies on the identity and quantity of urinary metabolites. This recommendation is coordinated with the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute of Environmental Health Sciences (NIEHS).

ii. *Rationale for recommendation.* The CPSC is requesting that 6 non-phthalate plasticizers be added to the *Priority Testing List* because they need biomonitoring data on urinary metabolites. Phthalate plasticizers are being replaced with non-phthalate plasticizers, such as acetyl tri-*n*-butyl citrate (Chemical Abstract Service Registry Number (CAS No.) 77-90-7); di(2-ethylhexyl) adipate (CAS No. 103-23-1); di(2-ethylhexyl) terephthalate (CAS No. 6422-86-2); 2,2,4-trimethyl-1,3-pentanediol diisobutyrate (CAS No. 6846-50-0); 1,2-cyclohexanedicarboxylic acid, 1,2-diisononyl ester (CAS No. 16612-78-8); and 1,2-cyclohexanedicarboxylic acid, 1,2-dinonyl ester, branched and linear ester (CAS No. 474919-59-0) (Table 2 of this unit). The 6 non-phthalate plasticizers identified in Table 2 of this unit are known to be used in children's

products, including teething rings and soft plastic toys and have the potential to migrate from these products into human saliva.

In addition, the CPSC is requesting that 25 phosphate ester flame retardants and 2 other flame retardants be added to the *Priority Testing List* because they need biomonitoring data on urinary metabolites. The flame retardants identified in Tables 3A, 3B, and 4 of this unit are known to be used in upholstered furniture, automobile upholstery, and children's products such as car seats, play pens, and toys. These flame retardants are substitutes for pentabromodiphenyl ether, which was withdrawn from the market due to environmental and health concerns.

iii. *Supporting information--a. Non-phthalate plasticizers.* The non-phthalate plasticizer, di(2-ethylhexyl) adipate (CAS No. 103-23-1) was added to the *Priority Testing List* in the 28<sup>th</sup> ITC Report (Ref. 4). Di(2-ethylhexyl) adipate was recommended for chemical fate, ecological effects, and health effects testing because of extensive human and environmental exposures. Di(2-ethylhexyl) adipate was removed from the *Priority Testing List* in the 32<sup>nd</sup> ITC Report because manufacturers committed to develop dossiers and necessary test data under the Screening Information Data Set (SIDS) program of the Organization for Economic Cooperation and Development (OECD) (Ref. 5). Di(2-ethylhexyl) terephthalate (CAS No. 6422-86-2) was added to the *Priority Testing List* in the 11<sup>th</sup> ITC Report as bis(2-ethylhexyl) terephthalate (Ref. 6). Di(2-ethylhexyl) terephthalate was recommended for chemical fate, ecological effects, and health effects testing because of extensive human and environmental exposures. Di(2-ethylhexyl) terephthalate was removed from the *Priority Testing List* in the 13<sup>th</sup> ITC Report (Ref. 7). Di(2-ethylhexyl) terephthalate was removed because EPA developed a



Negotiated Testing Agreement with the chemical's manufacturers to conduct the testing (Ref. 8). 2,2,4-Trimethyl-1,3-pentanediol diisobutyrate (CAS No. 6846-50-0) has been reviewed by OECD and a SIDS dossier has been developed (<http://www.inchem.org/documents/sids/sids/6846500.pdf>). 1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester (CAS No. 166412-78-8) is a plasticizer for "PVC and other polar polymers and can be used in applications that are particularly sensitive from a toxicological point of view" ([http://www2.basf.us/plasticizers/pdfs/Hex\\_DINCH\\_e\\_08\\_04.pdf](http://www2.basf.us/plasticizers/pdfs/Hex_DINCH_e_08_04.pdf)). 1,2-Cyclohexanedicarboxylic acid, 1,2-dinonyl ester, branched and linear (CAS No. 474919-59-0) is a plasticizer that is "recommended for medical products, toys and food packaging applications." Dreyfus and Babich have demonstrated that all six of these non-phthalate plasticizers migrate into simulated saliva (Ref. 9).

b. *Phosphate ester flame retardants*. Tributyl phosphate (CAS No. 126-73-8) was recommended with intent to designate in the 18<sup>th</sup> ITC Report (Ref. 10). Tributyl phosphate was recommended for chemical fate, ecological effects, and health effects testing because of extensive human and environmental exposures. Tributyl phosphate was also added to the May 19, 1986 PAIR and HaSDR rules (Ref. 11). After reviewing extensive voluntary data submissions from manufacturers and reports submitted in response to the May 19, 1986 PAIR and HaSDR rules, the ITC designated tributyl phosphate for chemical fate, ecological effects, and health effects testing in the 19<sup>th</sup> ITC Report (Ref. 12). Tributyl phosphate was removed from the *Priority Testing List* in the 22<sup>nd</sup> ITC Report (Ref. 13). Tributyl phosphate was removed from the *Priority Testing List* because EPA proposed the testing designated by the ITC in a NPRM that was

published on November 12, 1987 (Ref. 14). EPA required the testing designated by the ITC in a final rule published on August 14, 1989 (Ref. 15).

Tributyl phosphate (CAS No. 126-73-8), triisobutyl phosphate (CAS No. 126-71-6) and tri(2-butoxyethyl) phosphate (CAS No. 78-51-3) were recommended for chemical fate testing and added to the *Priority Testing List* in the 26<sup>th</sup> ITC Report (Ref. 16).

Tributyl phosphate was also recommended for ecological effects testing (plant toxicity testing) in the 26<sup>th</sup> ITC Report. Tributyl phosphate, triisobutyl phosphate, and tri(2-butoxyethyl) phosphate were added to the September 28, 1990 PAIR and HaSDR rules (Ref. 17). After reviewing reports and studies submitted in response to the September 28, 1990 PAIR and HaSDR rules, tributyl phosphate, triisobutyl phosphate and tri(2-butoxyethyl) phosphate were removed from the *Priority Testing List* in the 33<sup>rd</sup> ITC Report (Ref. 18). Tributyl phosphate was removed from the *Priority Testing List* because testing was being conducted in response to the August 14, 1989 final rule. Triisobutyl phosphate was removed from the *Priority Testing List* because it was not known to be domestically produced or imported in substantial quantities. Tri (2-butoxyethyl) phosphate was removed from the *Priority Testing List* because it was not a high priority for testing at that time.

Triphenyl phosphate (CAS No. 115-86-6) was added to the *Priority Testing List* in the 2<sup>nd</sup> ITC Report as one of the chemicals in the aryl phosphates category (Ref. 19). The testing recommendations for the aryl phosphates category included carcinogenicity, mutagenicity, teratogenicity, other chronic effects, environmental effects, and epidemiology. Triphenyl phosphate was added to the June 22, 1982 PAIR rule (Ref. 20) and the September 2, 1982 HaSDR rule (Ref. 21). Triphenyl phosphate was removed

from the *Priority Testing List* in the 14<sup>th</sup> ITC Report (Ref. 22). Triphenyl phosphate was removed from the *Priority Testing List* because the aryl phosphates category was included in a December 29, 1983 Advanced Notice of Proposed Rulemaking (ANPRM) (Ref. 23). Triphenyl phosphate was also included in a January 17, 1992 NPRM (Ref. 24).

Tris(2-chloroethyl) phosphate (CAS No. 115-96-8) was added to the *Priority Testing List* in the 23<sup>rd</sup> ITC Report (Ref. 25). Tris(2-chloroethyl) phosphate was recommended for chemical fate and ecological effects testing. Tris(2-chloroethyl) phosphate was added to the November 16, 1988 PAIR and HaSDR rules (Ref. 26). After reviewing reports and studies submitted in response to the November 16, 1988 PAIR and HaSDR rules, tris(2-chloroethyl) phosphate was removed from the *Priority Testing List* in the 36<sup>th</sup> ITC Report (Ref. 27). Tris(2-chloroethyl) phosphate was removed from the *Priority Testing List* because the data or structure activity relationships considered by the ITC did not indicate a need for further testing at that time.

Tris(1,3-dichloro-2-propyl) phosphate (CAS No. 13674-87-8), tris(2-chloro-1-propyl) phosphate (CAS No. 6145-73-9), and tris(1-chloro-2-propyl)phosphate (CAS No. 13674-84-5) were added to the *Priority Testing List* in the 23<sup>rd</sup> ITC Report (Ref. 25). The 3 phosphate ester flame retardants were recommended for chemical fate, ecological effects, and health effects testing because of extensive human and environmental exposures. The three phosphate ester flame retardants were included in the November 16, 1988 PAIR and HaSDR rules (Ref. 26). Several chemical fate, ecological effects and health effects studies were submitted to EPA under the HaSDR rule. The sunset date for submitting studies under the HaSDR rule was December 16, 1998. The three phosphate ester flame retardants were removed from the *Priority Testing List* in the 36<sup>th</sup> ITC Report

because the data or structure activity relationships considered by the ITC did not indicate a need to designate the chemicals for further testing at that time (Ref. 27). Tris(1,3-dichloro-2-propyl) phosphate has been identified as a probable human carcinogen, and tris(chloropropyl) phosphate (mixture of isomers), see Table 3B, an analog to tris(1,3-dichloro-2-propyl) phosphate, is being tested by the National Toxicology Program (NTP). The phosphate ester flame retardant bis(2-chloropropyl) (1-chloro-2-isopropyl) phosphate (CAS No. 76649-15-5) was added to the *Priority Testing List* in the 30<sup>th</sup> ITC Report (Ref. 28). Bis(2-chloropropyl) (1-chloro-2-isopropyl) phosphate is a component of tris(chloropropyl) phosphate (mixture of isomers). Bis(2-chloropropyl) (1-chloro-2-isopropyl) phosphate was recommended for chemical fate, ecological effects and health effects testing because of potential human and environmental exposures and included in the May 14, 1993 PAIR and HaSDR rules (Ref. 29). A few studies were submitted to EPA under the HaSDR rule. Bis(2-chloropropyl) (1-chloro-2-isopropyl) phosphate was removed from the *Priority Testing List* in the 36<sup>th</sup> ITC Report because the data or structure activity relationships considered by the ITC did not indicate a need to designate the chemical for further testing at that time (Ref. 27).

c. *Other flame retardants.* The Brominated Phthalates Panel of the American Chemistry Council submitted its test plan for bis(2-ethyl-1-hexyl) tetrabromophthalate (CAS No. 26040-51-7) to the EPA's HPV Challenge Program on July 23, 2004 (<http://www.epa.gov/hpv/pubs/summaries/phthacid/c15484.pdf>). Partially as a result of this submission, there are numerous data available for bis(2-ethyl-1-hexyl) tetrabromophthalate (<http://iaspub.epa.gov/opptppv/quicksearch.display?pChem=102247>). Toxicological data

on 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (CAS No.183658-27-7) could not be located by California's Office of Health Hazard Assessment

(<http://oehha.ca.gov/multimedia/biomon/pdf/120408flamedoc.pdf>). Bis(2-ethyl-1-hexyl) tetrabromophthalate and 2-ethylhexyl-2,3,4,5-tetrabromobenzoate are components of Firemaster®550, a flame-retardant substitute for pentabromodiphenyl ether.

iv. *Information needs.* The CPSC needs biomonitoring data on the identity and quantity of urinary metabolites for the 6 non-phthalate plasticizers, 25 phosphate ester flame retardants and 2 other flame retardants listed in Tables 2, 3A, 3B, and 4 of this unit. Specifically, CPSC is seeking information that would help to estimate human exposure to these compounds. First, CPSC needs studies on the metabolism of these compounds in animals or humans, including the identification of metabolites present in human urine, blood or other fluids. For the citrates and phosphates, urinary metabolites may include diesters; for adipate the metabolites may include the monoester. Second, CPSC needs studies that measure the amount of metabolite present in human urine or other media. Third, CPSC needs quantitative studies of metabolism in animals or humans that would allow one to estimate total exposure from metabolite levels.

**TABLE 2.--NON-PHTHALATE PLASTICIZERS BEING ADDED TO THE *PRIORITY TESTING LIST***

<b>CAS No.</b>	<b>Plasticizer</b>
77-90-7	1,2,3-Propanetricarboxylic acid, 2-(acetyloxy)-, tributyl ester; Acetyl tri- <i>n</i> -butyl citrate
103-23-1	Hexanedioic acid, 1,6-bis(2-ethylhexyl) ester; Di(2-ethylhexyl) adipate
6422-86-2	1,4-Benzenedicarboxylic acid, 1,4-bis(2-ethylhexyl) ester; Di(2-ethylhexyl) terephthalate
6846-50-0	Propanoic acid, 2-methyl-, 1,1'-[2,2-dimethyl-1-(1-methylethyl)-1,3-propanediyl] ester; 2,2,4-Trimethyl-1,3-pentanediol diisobutyrate
166412-78-8	1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester

474919-59-0	1,2-Cyclohexanedicarboxylic acid, 1,2-dinonyl ester, branched and linear
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**TABLE 3A.--PHOSPHATE ESTER FLAME RETARDANTS BEING ADDED TO THE *PRIORITY TESTING LIST***

<b>CAS No.</b>	<b>Flame Retardant</b>
78-40-0	Phosphoric acid, triethyl ester; Triethyl phosphate
78-51-3	Ethanol, (2-butoxy-), 1,1',1''-phosphate; Tri(2-butoxyethyl) phosphate
115-86-6	Phosphoric acid, triphenyl ester; Triphenyl phosphate
115-96-8	Ethanol, 2-chloro-, phosphate (3:1); Tris-(2-chloroethyl) phosphate
126-71-6	Phosphoric acid, tris(2-methylpropyl) ester; Triisobutyl phosphate
126-73-8	Phosphoric acid tributyl ester; Tributyl phosphate
1241-94-7	Phosphoric acid, 2-ethylhexyl diphenyl ester; 2-Ethylhexyl diphenyl phosphate
1330-78-5	Phosphoric acid, tris(methylphenyl) ester; Tricresyl phosphate, mixed isomers
5945-33-5	Phosphoric acid, <i>P,P'</i> -[(1-methylethylidene)di-4, 1-phenylene] <i>P,P,P',P'</i> -tetraphenyl ester; Tetraphenyl Bisphenol A diphosphate
6145-73-9	1-Propanol, 2-chloro-, 1,1',1''-phosphate; Tris(2-chloro-1-propyl)phosphate
13674-84-5	2-Propanol, 1-chloro-, 2,2'2''-phosphate; Tris(1-chloro-2-propyl) phosphate
13674-87-8	2-Propanol, 1,3-dichloro-, phosphate (3:1); Tris(1,3-dichloro-2-propyl) phosphate
25155-23-1	Phenol, dimethyl-, 1,1',1''-phosphate; Trixylyl phosphate
26444-49-5	Phosphoric acid, methylphenyl diphenyl ester; Cresyl diphenyl phosphate
29761-21-5	Phosphoric acid, isodecyl diphenyl ester; Isodecyl diphenyl phosphate
38051-10-4	Phosphoric acid, <i>P,P'</i> -[2,2-bis(chloromethyl)-1,3-propanediyl] <i>P,P,P',P'</i> -tetrakis(2-chloroethyl) ester; 2,2-Bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) phosphate
56803-37-3	Phosphoric acid, (1,1-dimethylethyl)phenyl diphenyl ester; tert-Butylphenyl diphenyl phosphate
65652-41-7	Phosphoric acid, bis[(1,1-dimethylethyl)phenyl] phenyl ester; Bis (tert-butylphenyl) phenyl phosphate
68937-41-7	Phenol, isopropylated, phosphate (3:1); Isopropylated triphenyl phosphate
68937-40-6	Phenol, isobutylated, phosphate (3:1); Isobutylated phenol phosphate
76025-08-6	Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester; Bis(1-chloro-2-isopropyl) (2-chloropropyl) phosphate
76649-15-5	Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester; Bis(2-chloropropyl) (1-chloro-2-isopropyl) phosphate

181028-79-5	Phosphoric trichloride, reaction products with bisphenol <i>A</i> and phenol; Bisphenol A diphosphate
220352-35-2	Phenol, tert-Bu derivs., phosphates (3:1); Butylated triphenyl phosphate

**TABLE 3B.--THE PHOSPHATE ESTER FLAME RETARDANT, TRIS(CHLOROPROPYL) PHOSPHATE (MIXTURE OF ISOMERS), BEING ADDED TO THE *PRIORITY TESTING LIST***

CAS No.	Tris(Chloropropyl) Phosphate Isomers
6145-73-9	1-Propanol, 2-chloro-, 1,1',1''-phosphate
13674-84-5	2-Propanol, 1-chloro-, 2,2',2''-phosphate
76025-08-6	Phosphoric acid, bis(2-chloro-1-methylethyl) 2-chloropropyl ester
76649-15-5	Phosphoric acid, 2-chloro-1-methylethyl bis(2-chloropropyl) ester

**TABLE 4.--OTHER FLAME RETARDANTS BEING ADDED TO THE *PRIORITY TESTING LIST***

CAS No.	Flame Retardant
26040-51-7	1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester; Bis(2-ethyl-1-hexyl) tetrabromophthalate
183658-27-7	Benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester; 2-Ethylhexyl-2,3,4,5-tetrabromobenzoate

3. *Chemicals to which children living near hazardous waste sites may be exposed-*

-i. *Recommendation.* ATSDR requests that the ITC add nine chemicals to which children living near hazardous waste sites may be exposed to the *Priority Testing List* to obtain biomonitoring studies on these chemicals.

ii. *Rationale for recommendation.* ATSDR is requesting nine chemicals to which children living near hazardous waste sites may be exposed be added to the *Priority Testing List* because children constitute a particularly vulnerable population of individuals, who, based upon their increased time outdoors and playtime behaviors, have a potentially higher than normal exposure to these chemicals around hazardous waste sites. For the chemicals in Table 5 of this unit, there is insufficient information available concerning both background levels and possible elevated exposure levels for children.

iii. *Supporting information.* ATSDR works closely with the Center for Disease Control and Prevention's National Center for Environmental Health (NCEH), (<http://www.cdc.gov/nceh>), in their biomonitoring program known as the National Report on Human Exposure to Environmental Chemicals (NHANES), (<http://www.cdc.gov/nchs/nhanes.html>). At least three of the chemicals in Table 5 of this unit have been included in past NHANES: 1,1-dichloroethane (CAS No. 75-34-3); 1,1,2,2-tetrachloroethane (CAS No. 79-34-5); and 1,2-dichloroethane (CAS No. 107-06-2). In the NHANES 2003–2004 subsample: 1,1-dichloroethane (CAS No. 75-34-3); 1,1,2,2-tetrachloroethane (CAS No. 79-34-3); and 1,2-dichloroethane (CAS No. 107-06-2) were detectable in less than a few percent of the participants. In a non-representative sample of adults in NHANES III (1988-1994), blood levels were also non-detectable or detected in <10% of samples. ATSDR needs to know if children living near hazardous waste sites have elevated blood levels of the chemicals in Table 5 of this unit.

1,1-Dichloroethane was added to the *Priority Testing List* in the 32<sup>nd</sup> ITC Report because it was recommended for dermal absorption rate testing (Ref. 5). 1,1-Dichloroethane was also added to the *Priority Testing List* in the 55<sup>th</sup> ITC Report because it was a HPV chemical that was not sponsored for testing (Ref. 30). 1,1-Dichloroethane was removed from the *Priority Testing List* in the 56<sup>th</sup> ITC Report because it was no longer a HPV chemical (Ref. 31). 1,1-Dichloroethane's toxicity includes effects on the heart, such as irregular heartbeats, which prompted discontinuing its use as a surgical anesthetic. It is also known to cause kidney disease after long-term high exposure and has delayed growth in offspring of experimental animals exposed to high concentrations during pregnancy.



1,1,2,2-Tetrachloroethane has been observed to cause liver damage in experimental animals exposed to lower doses for long periods.

Benzidine (CAS No. 92-87-5), determined by the Department of Health and Human Services (HHS), World Health Organization (WHO) and EPA to be a carcinogen, can increase the risk of urinary bladder cancer in long term occupational exposures.

1,2-Dibromomethane (CAS No. 106-93-4) has been found to cause reproductive effects in some male workers including sperm damage. Experimental animal studies found birth defects in the young of animals exposed while *in utero*.

Acrolein (CAS No. 107-02-8) was added to the *Priority Testing List* in the 27<sup>th</sup> ITC Report as 1 of 89 aldehydes (Ref. 32). Acrolein was recommended for ecological effects testing because there were insufficient data to reasonably determine or predict the ecological effects of aldehydes that were submitted to the EPA as new chemicals.

Acrolein was removed from the *Priority Testing List* in the 45<sup>th</sup> ITC Report (Ref. 33).

Acrolein was removed because it was added to the OECD HPV Chemical Program ([http://webnet.oecd.org/Hpv/UI/SIDS\\_Details.aspx?id=6E4A94A8-0068-4088-8CF7-C193F61012D0](http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=6E4A94A8-0068-4088-8CF7-C193F61012D0)). Acrolein is a component of tobacco smoke and animal studies have found that inhaling it causes irritation to the nasal cavity and damage to the lining of lungs. Oral exposure through drinking water can cause stomach irritations, ulcers, and bleeding.

1,2-Dichloroethane (a.k.a. ethylene dichloride) was added to the *Priority Testing List* in the 35<sup>th</sup> ITC Report because it was recommended for dermal absorption rate testing (Ref. 34). 1,2-Dichloroethane was removed from the *Priority Testing List* in the

45<sup>th</sup> ITC Report (Ref. 33). 1,2-Dichloroethane was removed from the *Priority Testing List* because EPA published a June 9, 1999 NPRM for dermal absorption rate testing (Ref. 35). 1,2-Dichloroethane has been found to cause nervous system disorders, liver, and kidney disease and lung effects in humans ingesting or inhaling large amounts. It has also been found to cause kidney disease in experimental animals that ingested low doses.

Phenol (CAS No. 108-95-2) was added to the *Priority Testing List* in the 27<sup>th</sup> ITC Report because of its very high production volume, potential for release, and presence in commercial and consumer products (Ref. 32). Phenol was removed from the *Priority Testing List* because EPA proposed the testing designated by the ITC in a test rule that was published on November 22, 1993 (Ref. 36). Phenol, which is used as an antiseptic at low doses, can cause lung irritation, headaches and burnings eyes if inhaled at high doses. Repeated exposures can induce muscle tremors and loss of coordination, and high exposures in air for several weeks can cause paralysis, severe injury to the heart, liver, kidneys, and lungs.

Cresols (CAS No. 1319-77-3) were added to the *Priority Testing List* in the 1<sup>st</sup> ITC Report because their wide use as industrial solvents caused concerns for substantial occupational exposures (Ref. 37). Cresols were removed from the *Priority Testing List* in the 13<sup>th</sup> ITC Report (Ref. 7). Cresols were removed from the *Priority Testing List* because EPA proposed the testing designated by the ITC in a test rule that was published on July 11, 1983 (Ref. 38). Cresols were again added to the *Priority Testing List* in the 61<sup>st</sup> ITC Report to obtain dermal sensitization data (Ref. 39). Cresols were removed from the *Priority Testing List* in the 62<sup>nd</sup> ITC Report because the Cresols Panel of the American Chemistry Council submitted studies that met the ITC's data needs

(Ref. 40). Cresols at high levels for even short exposures can cause irritation of the eyes, nose, and throat. Skin contact with high levels can burn the skin and can damage the kidneys, liver, blood, lungs, and brain. Experimental animal studies found lesions in the nose and thyroid gland via food exposure.

Exposure to large amounts of aluminum (CAS No. 7429-90-5) dust can cause lung problems and decreased performance in some tests that measure functions of the nervous system. Also, some people with kidney disease can store a lot of aluminum in their bodies and sometimes develop bone or brain diseases which may be caused by the excess aluminum.

*iv. Information needs.* For the chemicals listed in Table 5 of this unit, ATSDR needs blood levels in children not living near hazardous waste sites and in children living near hazardous waste sites. ATSDR needs these data to determine if the children living near hazardous waste sites have elevated levels of these chemicals and may be more susceptible to their toxic effects.

**TABLE 5.--CHEMICALS TO WHICH CHILDREN LIVING NEAR HAZARDOUS WASTE SITES MAY BE EXPOSED**

<b>CAS No.</b>	<b>Chemical</b>
75-34-3	Ethane, 1,1-dichloro-; 1,1-Dichloroethane
79-34-5	Ethane, 1,1,2,2-tetrachloro-; 1,1,2,2-Tetrachloroethane
92-87-5	[1,1'-Biphenyl]-4,4'diamine; Benzidine
106-93-4	Ethane, 1,2-dibromo-; 1,2-Dibromoethane
107-02-8	2-Propenal; Acrolein
107-06-2	Ethane, 1,2-dichloro-; 1,2-Dichloroethane
108-95-2	Phenol
1319-77-3	Phenol, methyl-; Cresol
7429-90-5	Aluminum

4. *Diisocyanates and related compounds--i. Recommendation.* The EPA requests that the ITC add the category of 69 diisocyanates and related compounds to the *Priority*

*Testing List* to obtain use, fate, and exposure studies on uncured (unreacted)

diisocyanates and their related compounds that are used in the manufacture of, and present in, products.

ii. *Rationale for recommendation.* EPA is concerned about diisocyanates and related compounds in the manufacture and use of products that may result in exposures to consumers, children, and the general population. Diisocyanates are well known dermal and inhalation sensitizers in the workplace and have been documented to cause asthma, lung damage, and in severe cases, fatal reactions. EPA is especially concerned about the potential health effects that may result from exposures to the consumer or self-employed worker while using products containing uncured diisocyanates (e.g., spray applied foam insulation (rigid foam), sealants, adhesives, paints, floor finishes, and coatings) and incidental exposures to the children and the general population while such products are used in or around buildings including homes or schools (for example on floors and athletic tracks) before the product has fully reacted and cured.

In April 2011, EPA published Action Plans for toluene diisocyanate (TDI) and 5 related compounds (<http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/tdi.pdf>) and methylene diphenyl diisocyanate (MDI) and 7 related compounds (<http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/mdi.pdf>). These Action Plans outline EPA's screening-level review of available hazard and exposure information on uncured (unreacted) MDI, TDI, and 12 additional related compounds. However, after further review, EPA recognizes that aspects of an exposure scenario to consumers are generally applicable to many diisocyanate compounds. Therefore, in addition to the 14 diisocyanates and related compounds listed in the Action Plans, EPA identified 29

aromatic and 26 aliphatic diisocyanate compounds, such as hexamethylene diisocyanate (HDI). These 29 aromatic and 26 aliphatic diisocyanate compounds are used in sealants, coatings, spray foams, elastomers or adhesives and may be substituted in such products for the 14 diisocyanates and related compounds listed in the Action Plans. The ITC is adding the 14 diisocyanates and related compounds listed in the Action Plans and the 29 aromatic and 26 aliphatic diisocyanate compounds to the *Priority Testing List* to provide a more comprehensive approach to assessing hazard and exposure information for diisocyanates and related compounds. The 14 diisocyanates and related compounds listed in the Action Plans and the 29 aromatic and 26 aliphatic diisocyanate compounds are identified in Table 6 of this unit.

ITC is recommending that the 69 diisocyanates and related compounds be added to the TSCA section 8(d) HaSDR rule to facilitate EPA's ability to obtain existing studies. Studies obtained on these chemicals may provide updated information from prior requests and assist EPA in taking appropriate action(s) to protect consumers, commercial workers, and other affected citizens from exposure to uncured diisocyanate-containing products during their use. In addition, any updated information may assist EPA in taking appropriate action(s) to protect bystanders and building occupants, including children from inadvertent exposure to diisocyanates and related compounds that might be released during and after application of diisocyanate-containing products.

The ITC recommended priority consideration of isocyanates as part of the 26<sup>th</sup> ITC Report (Ref. 16). EPA subsequently issued a TSCA section 8(d) HaSDR rule for these chemicals on September 28, 1990 (Ref. 17). Given the time elapsed since that reporting rule was issued, the changes in the industry, and the increased use of

diisocyanate-containing products, EPA believes issuing another rule that would require reporting of unpublished health and safety studies that were not previously submitted is appropriate.

iii. *Supporting information--a. Health.* Most of the data on human health hazards resulting from diisocyanate exposures are based on occupational populations. These data indicate that exposure to diisocyanates can cause contact dermatitis, skin and respiratory tract irritation, immune sensitization, and asthma (Ref. 41). It is well documented that isocyanate exposure is an attributable cause of work-related asthma, and prevalence in the exposed workforce is estimated at 1-20% (Refs. 42 and 43).

Occupational skin exposures in workers exposed to MDI are of concern because isocyanate sensitization and/or asthma has occurred in cases where the potential for skin exposure is substantial, but measured airborne MDI monomer levels are below occupational exposure levels (OELs) or below the limits of detection with the methods used, or where similar MDI levels would be expected but MDI air monitoring data are not available (Refs. 44-48).

The minimum exposure to isocyanates that can elicit sensitization responses or asthma is not known. In addition, immune response and subsequent disease in humans can be quite variable (Ref. 49). Fatalities linked to occupational diisocyanate exposures in sensitized persons have been reported (Refs. 50 and 51).

Cross-sensitization has been observed between MDI, TDI, HDI, and dicyclohexylmethane diisocyanate (HMDI) in mice, and between MDI, TDI, and HDI in humans (Ref. 52).

Animal data indicate that MDI may be carcinogenic; however, a consistent association has not been reported in epidemiologic studies (Refs. 53 and 54). Animal data indicate that TDI may be carcinogenic (Ref. 55). HDI was negative for carcinogenicity in a 2-year bioassay in rats (Ref. 56).

b. *Exposure.* In contrast to the large amount of exposure data available for professional workers who work with diisocyanates, EPA is hoping to obtain additional exposure data characterizing the use and exposure scenarios of consumer and commercial products containing uncured diisocyanates. In addition, comparing concentrations to which the consumer and general population is or can be exposed with existing workplace exposure limits to determine overexposure is not appropriate because the OSHA permissible exposure limits (PELs) are not intended to protect consumers and the general population (Ref. 49).

Until polyurethane products fully cure, there may be the potential for inhalation and dermal exposure. These exposures may result from direct use of products or from bystander exposure. The use of spray polyurethane foam insulation (rigid foam) products has resulted in personal and area air samples of MDI above the OSHA PEL (Refs. 57-60). Potential bystander exposures to TDI products have been found in the literature, including emissions of TDI from concrete patio sealants (Refs. 61 and 62). Levels of moisture curing polyurethanes, including TDI were found in air hallway samples of an apartment building when the moisture curing polyurethanes were being used (Ref. 63). There were emissions during emergency response of an overturned truck carrying TDI (Ref. 64), and para-occupational exposure for secretaries and janitors who worked in the vicinity of but not directly with TDI (Ref. 65).

Unbound aliphatic isocyanates used in coatings may remain on the surface of curing coating products, like paint, for up to several weeks (Ref. 47). In addition, there is potential for significant exposures to aliphatic isocyanates for direct users and bystanders in the auto refinishing and auto repair industry (Ref. 66).

Children exposed to the same airborne concentrations of MDI as adults may receive a larger dose because children take more breaths per minute and have a higher relative tidal volume. An accidental acute exposure of children to high levels of MDI in a polyurethane sealant used on a school athletic track was associated with asthma-like symptoms, including among children with no prior history of respiratory dysfunction (Ref. 67). Children with asthma are an especially vulnerable population for exposure; they are more susceptible to inflammatory narrowing of the airways, which results in a proportionally greater obstruction of their smaller respiratory system (Refs. 68 and 69).

Additional data characterizing the concentration of diisocyanates and related compounds in the air during and after use of products that may result in dermal, eye, or inhalation exposures to uncured diisocyanates will be helpful to the Agency. It would be helpful to receive additional information on the extent factors such as application techniques, product composition, ambient conditions, and method of measurement that influence the availability of uncured diisocyanates. EPA is also aware that there is uncertainty about the curing time of various products under different situations and that additional data could help address certain concerns, such as re-entry time, which are important for improving communication to prevent exposure.

*c. Ecotoxicity.* Although there is a moderate acute ecotoxicity profile for MDI and TDI, the hazards associated with exposures to these chemicals have centered on human



health effects not ecological effects. Experimental ecotoxicological data for MDI and TDI and their degradation products indicate moderate to low toxicity to aquatic organisms (Refs. 57 and 70-73). Other toxicity data suggest low likelihood of effects to terrestrial biota such as plants and earthworms (Refs. 74 and 75).

*iv. Information needs.* Information is needed on diisocyanates and related compounds used to formulate a broad class of polyurethane products (e.g., sealants, adhesives, etc.) that are intended to further react upon end-use. Information is also needed on the percent of diisocyanates remaining, if any, in the final products, and/or studies that assess exposure to uncured (unreacted) diisocyanates. Studies are needed that provide information on the inhalation, dermal, and eye exposure potential and/or exposure levels for various populations; e.g., workers, consumers, bystanders, and building occupants, including children (through characterizing concentrations of diisocyanates in indoor air, outdoor air, blood, or urine) during and after use of products containing uncured diisocyanates. Studies are also needed on induction of sensitization, asthma development, other lung or health effects (irritation to the mucous membranes of the eyes and gastrointestinal and respiratory tracts, chest tightness, cough, nasal congestion, death), biomarkers of recent and long-term exposure to diisocyanates, and the contributory nature of skin exposure to the development of diisocyanate asthma.

Also needed are dermal exposure assessments in terms of dermal exposure potential and extent of exposure to diisocyanates during diisocyanate-containing product use in occupational as well as non-occupational (e.g., consumer use) settings. Although some techniques and methods have been developed to measure human skin exposure to diisocyanates, these techniques and methods have several limitations. Consequently

studies that provide improved qualitative and quantitative methods for detecting and quantifying skin exposures to diisocyanates and any associated data on measured exposures are required. Studies investigating associations between dermal exposure to diisocyanates and individual differences in metabolism with biomarkers of exposure would also provide useful information for exposure assessment. Additionally, studies are needed that characterize uncured diisocyanate levels within products over time. Background conditions and information on frequency and duration (use patterns) to diisocyanates are also needed.

EPA is also interested in obtaining studies that contain information on sampling and analytical methods under development for dermal exposures; methods for assessing exposure to total reactive diisocyanates; methods and techniques to determine potential dermal exposure and uptake of diisocyanates through the skin; biological monitoring methods for estimating exposure to diisocyanates through all routes of exposure; and efficacy of currently used personal protective equipment in protecting workers and other populations during product use.

Specifically, EPA is interested in health and safety studies evaluating professional-, commercial-, and consumer-use products containing uncured diisocyanates with special emphasis on the following types of studies:

- a. Inhalation monitoring studies characterizing potential worker and consumer exposures including associated airborne levels of total reactive diisocyanates and other chemicals.

b. Inhalation monitoring studies characterizing incidental exposures of bystanders and building occupants including associated airborne levels of total reactive diisocyanates and other chemicals.

c. Industrial hygiene or epidemiological assessments of dermal exposure to uncured diisocyanate-containing products in occupational settings as well as for consumers, including impact of curing time on such exposures.

d. Studies focusing on the contributory nature of skin exposure to the development of diisocyanate asthma in workers, consumers, and the general population, including modification of skin uptake of polyisocyanates by co-exposure to solvents and other agents or by skin cuts/abrasions.

e. Epidemiological studies that address induction of sensitization and asthma development and other observed health effects in exposed populations including exposure-response relationships. Also of interest is a discussion of factors that impact these processes, physiological or otherwise.

f. Studies on advances in biomonitoring for sensitive biological markers of recent and long-term exposure to diisocyanates including studies that associate dermal exposure and individual differences in metabolism with biomarkers.

g. Studies on recent developments and refinements in specific qualitative and quantitative techniques and methods for dermal exposure assessment including and beyond those currently available (e.g., pads, wipes, and tape stripping methods).

h. Studies that have used emission testing protocols (environmental chambers) for sample testing that provide levels of uncured diisocyanates over time and associated

curing rates in accordance with specific humidity and temperature levels and ventilation rates and/or building re-occupancy guidance after installation or use of products.

i. Studies that provide information on new or under development sampling and analytical methods for total reactive diisocyanates in diverse media (vapor, aerosol, dust, hard surfaces) including studies that provide details of industry methods.

j. Studies with information on testing protocols currently in use or in development for air monitoring, products testing, biomonitoring, or dermal exposure.

k. Field studies that report on ventilation rates in existing and new buildings and their relationship to detected airborne levels of chemicals.

l. Efficacy assessments of engineering control strategies such as dilution ventilation, local exhaust ventilation, and containment in reducing worker exposure as well as bystander/occupant exposure.

m. Efficacy assessments of personal protective equipment (PPE) used for exposure reduction, e.g., respirators, chemical protective suits, gloves, aprons, overalls used by workers, and for specific types of PPE that could be used by consumers or bystanders.

EPA needs the information described in Unit IV.A.4. iv.a. through m. on the diisocyanates and related compounds, which are listed in Table 6 of this unit.

**Table 6.--DIISOCYANATES AND RELATED COMPOUNDS**

<b>CAS No.</b>	<b>Chemical Name</b>	<b>Action</b>
91-08-7	Benzene, 1,3-diisocyanato-2-methyl-	A, B
91-97-4	1,1'-Biphenyl, 4,4'-diisocyanato-3,3'-dimethyl-	A, C
101-68-8	Benzene, 1,1'-methylenebis[4-isocyanato-	A, D
104-49-4	Benzene, 1,4-diisocyanato-	A, C
123-61-5	Benzene, 1,3-diisocyanato-	A, C
139-25-3	Benzene, 1,1'-methylenebis[4-isocyanato-3-methyl-	C

584-84-9	Benzene, 2,4-diisocyanato-1-methyl-	A, B
822-06-0	Hexane, 1,6-diisocyanato-	A, E
2422-91-5	Benzene, 1,1',1''-methylidynetris[4-isocyanato-	A, C
2536-05-2	Benzene, 1,1'-methylenebis[2-isocyanato-	D
2778-42-9	Benzene, 1,3-bis(1-isocyanato-1-methylethyl)-	C
3173-72-6	Naphthalene, 1,5-diisocyanato-	C
3634-83-1	Benzene, 1,3-bis(isocyanatomethyl)-	C
3779-63-3	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(6-isocyanatohexyl)-	E
4035-89-6	Imidodicarbonic diamide, <i>N,N'</i> ,2-tris(6-isocyanatohexyl)-	A, E
4098-71-9	Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl-	A, E
4128-73-8	Benzene, 1,1'-oxybis[4-isocyanato-	C
5124-30-1	Cyclohexane, 1,1'-methylenebis[4-isocyanato-	A, E
5873-54-1	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl)methyl]-	A, D
7517-76-2	Cyclohexane, 1,4-diisocyanato-, trans-	E
9016-87-9	Isocyanic acid, polymethylenepolyphenylene ester	D
9017-01-0	Benzene, 1,3-diisocyanatomethyl-, homopolymer; TDI homopolymer	B
9019-85-6	Benzene, 1,3-diisocyanatomethyl-, trimer	C
10347-54-3	Cyclohexane, 1,4-bis(isocyanatomethyl)-	E
13622-90-7	Cyclohexane, 1,1'-methylenebis[4-isocyanato-, (trans,trans)-	E
15646-96-5	Hexane, 1,6-diisocyanato-2,4,4-trimethyl-	A, E
16325-38-5	Benzene, 1,2,4,5-tetrachloro-3,6-bis(isocyanatomethyl)-	C
16938-22-0	Hexane, 1,6-diisocyanato-2,2,4-trimethyl-	A, E
17589-24-1	1,3-Diazetidine-2,4-dione, 1,3-bis[4-[(4-isocyanatophenyl)methyl]phenyl]-	D
23370-68-5	1,3-Diazetidine-2,4-dione, 1,3-bis[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-	E
25686-28-6	Benzene, 1,1'-methylenebis[4-isocyanato-, homopolymer; MDI homopolymer	D
25854-16-4	Benzene, bis(isocyanatomethyl)-	A, C
26447-40-5	Benzene, 1,1'-methylenebis[isocyanato-	A, D
26471-62-5	Benzene, 1,3-diisocyanatomethyl-	A, B
26603-40-7	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(3-isocyanatomethylphenyl)-	A, B
26747-90-0	1,3-Diazetidine-2,4-dione, 1,3-bis(3-isocyanatomethylphenyl)-	A, B
28182-81-2	Hexane, 1,6-diisocyanato-, homopolymer; hexamethylene diisocyanate (HDI) homopolymer	E

31107-36-5	1,3-Diazetidin-2-one, 1,3-bis[4-[(4-isocyanatophenyl)methyl]phenyl]-4-[[4-[(4-isocyanatophenyl)methyl]phenyl]imino]-	D
38661-72-2	Cyclohexane, 1,3-bis(isocyanatomethyl)-	E
42170-25-2	Cyclohexane, bis(isocyanatomethyl)-	E
50639-37-7	2H-1,3,5-Oxadiazine-2,4,6(3H,5H)-trione, 3,5-bis(6-isocyanatohexyl)-	E
50830-59-6	1,3,4-Thiadiazole, 2-isocyanato-5-(trifluoromethyl)-, dimer	C
51508-06-6	1,3,4-Thiadiazole, 2-(1,1-dimethylethyl)-5-isocyanato-, dimer	C
53880-05-0	Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl-, homopolymer; Isophorone diisocyanate homopolymer	E
55525-54-7	Urea, N,N'-bis[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-	E
60732-52-7	Carbamic acid, N,N'-(3-isocyanatomethylphenyl)-, C,C'-(oxydi-2,1-ethanediyl) ester	C
65087-21-0	Carbamic acid, N-[4-[(4-isocyanatocyclohexyl)methyl]cyclohexyl]-, C,C'-(oxydi-2,1-ethanediyl) ester	E
65104-99-6	Imidodicarbonic diamide, 2,2'-[methylenebis(2-chloro-4,1-phenylene)]bis[N,N'-bis(3-isocyanatomethylphenyl)-	C
65105-00-2	Carbamic acid, N-(3-isocyanatomethylphenyl)-, C,C'-(1-methyl-1,3-propanediyl) ester	C
65105-02-4	Carbamic acid, N-(3-isocyanatomethylphenyl)-, C,C'-(1,4-butanediyl) ester	C
67873-91-0	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-	E
68083-39-6	Benzenamine, N,N'-methanetetraylbis[3-isocyanato-2,4,6-tris(1-methylethyl)-	C
68092-73-9	Carbamic acid, N-(3-isocyanatomethylphenyl)-, C,C'-(1,2-ethanediyl) ester	C
68092-74-0	Carbamic acid, N-(3-isocyanatomethylphenyl)-, C,C'-[oxybis(1-methyl-2,1-ethanediyl)] ester	C
68133-14-2	Carbamic acid, N-(3-isocyanatomethylphenyl)-, C,C'-[[[(diethoxyphosphinyl)methyl]imino]di-2,1-ethanediyl] ester	C
68239-06-5	Cyclohexane, 2-heptyl-3,4-bis(9-isocyanatononyl)-1-pentyl-	A, E
68310-46-3	Hexanoic acid, [[2-ethyl-2-[[[[[5-isocyanato-1(or 5)-(methoxycarbonyl)pentyl]amino]carbonyl]oxy]methyl]-1,3-propanediyl]bis(oxycarbonylimino)]bis[isocyanato-, 1,1'-dimethyl ester	E

68366-14-3	Carbamic acid, <i>N</i> -[5-isocyanato-2(or 4)-methylphenyl]-, <i>C,C'</i> -(1-methyl-1,3-propanediyl) ester	C
68555-56-6	1,3-Diazetidine-2,4-dione, 1,3-bis(4-isocyanato-3-methylphenyl)-	C
68975-84-8	Carbamic acid, <i>N</i> -[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-, <i>C,C'</i> -(oxydi-2,1-ethanediyl) ester	E
69878-18-8	Hexanoic acid, 2,6-diisocyanato-, 2-isocyanatoethyl ester	E
70024-76-9	Hexatriacontane, diisocyanato-, branched	E
70198-24-2	Undecane, 1,6,11-triisocyanato-	E
71130-76-2	Urea, <i>N</i> -(3-isocyanatomethylphenyl)- <i>N'</i> -[[[4-[[[(3-isocyanatomethylphenyl)amino]carbonyl]amino]phenyl]methyl]phenyl]-	C
71832-70-7	Carbamic acid, <i>N</i> -[4-[(4-isocyanatophenyl)methyl]phenyl]-, <i>C,C'</i> -(oxydi-2,1-ethanediyl) ester	C
75790-84-0	Benzene, 2-isocyanato-4-[(4-isocyanatophenyl)methyl]-1-methyl-	C
75790-87-3	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl)thio]-	C
85702-90-5	2,9,11,13-Tetraazanonadecanethioic acid, 19-isocyanato-11-(6-isocyanatohexyl)-10,12-dioxo-, <i>S</i> -[3-(trimethoxysilyl)propyl] ester	E
106790-31-2	Benzenamine, 4-isocyanato- <i>N,N</i> -bis(4-isocyanatophenyl)-2,5-dimethoxy-	C

Notes: A – Previously added to the ITC’s *Priority Testing List* in the 26<sup>th</sup> ITC Report (Ref. 16).

B – In the Toluene Diisocyanate (TDI) Action Plan

(<http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/tdi.pdf>).

C – One of the 29 aromatic diisocyanate compounds.

D – In the Methylene Diphenyl Diisocyanate (MDI) Action Plan

(<http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/mdi.pdf>).

E – One of the 26 aliphatic diisocyanate compounds.

## *B. Chemicals Removed from the Priority Testing List*

1. *Cadmium compounds.* As a result of EPA’s expanding the cadmium compounds category to include any chemical that contains cadmium as part of that chemical’s structure, the ITC is removing 103 cadmium compounds, but not cadmium from the *Priority Testing List*. The 103 cadmium compounds were listed in the 68<sup>th</sup> ITC Report (Ref. 2).

2. *HPV Challenge Program orphan chemicals.* Two hundred seventy HPV Challenge Program orphan chemicals were added to the *Priority Testing List* in the 55<sup>th</sup> ITC Report (Ref. 30) and 5 were added to the *Priority Testing List* in the 56<sup>th</sup> ITC Report (Ref. 31).

Thirty HPV Challenge Program orphan chemicals were removed from the *Priority Testing List* in the 56<sup>th</sup> ITC Report (Ref. 31). Eight HPV Challenge Program orphan chemicals were removed from the *Priority Testing List* in the 58<sup>th</sup> ITC Report (Ref. 76). Thirty-five HPV Challenge Program orphan chemicals were removed from the *Priority Testing List* in the 61<sup>st</sup> ITC Report (Ref. 39). One HPV Challenge Program orphan chemical was removed from the *Priority Testing List* in the 63<sup>rd</sup> ITC Report (Ref. 77). Twenty-nine HPV Challenge Program orphan chemicals were removed from the *Priority Testing List* in the 68<sup>th</sup> ITC Report (Ref. 2).

Fourteen HPV Challenge Program orphan chemicals are being removed from the *Priority Testing List* because they were included in the EPA's October 21, 2011 TSCA section 4 proposed test rule (Ref. 3). These 14 HPV Challenge Program orphan chemicals are listed in Table 7 of this unit.

**TABLE 7.--FOURTEEN HPV CHALLENGE PROGRAM ORPHAN CHEMICALS BEING REMOVED FROM THE *PRIORITY TESTING LIST***

<b>CAS No.</b>	<b>Chemical Name</b>
98-16-8	Benzenamine, 3-(trifluoromethyl)-
124-63-0	Methanesulfonyl chloride
460-00-4	Benzene, 1-bromo-4-fluoro-
542-92-7	1,3-Cyclopentadiene
928-72-3	Glycine, <i>N</i> -(carboxymethyl)-, disodium salt
28106-30-1	Benzene, ethenylethyl-
35203-06-6	Benzenamine, 2-ethyl-6-methyl- <i>N</i> -methylene-
35203-08-8	Benzenamine, 2,6-diethyl- <i>N</i> -methylene-
37734-45-5	Carbonochloridothioic acid, <i>S</i> -(phenylmethyl) ester



37764-25-3	Acetamide, 2,2-dichloro- <i>N,N</i> -di-2-propenyl-
65996-91-0	Distillates (coal tar), upper
68153-60-6	Fatty acids, tall-oil, reaction products with diethylenetriamine, acetates
68442-77-3	2-Butenediamide, (2E)-, N1,N4-bis[2-(4,5-dihydro-2-nortall-oil alkyl-1H-imidazol-1-yl)ethyl] derivs.
68909-77-3	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. Residues

## V. References

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## **VI. The TSCA Interagency Testing Committee**

### ***Statutory Organizations with Representatives***

Department of Commerce

National Institute of Standards and Technology  
Dianne L. Poster, Alternate

Environmental Protection Agency  
Robert W. Jones, Member  
John E. Schaeffer, Alternate

National Institute of Environmental Health Sciences  
Nigel Walker, Member  
Scott Masten, Alternate

National Institute for Occupational Safety and Health  
Gayle DeBord, Member  
Dennis W. Lynch, Alternate

Occupational Safety and Health Administration  
Thomas Nerad, Member  
Janet Carter, Alternate

### ***Liaison Organizations with Representatives***

Agency for Toxic Substances and Disease Registry  
Glenn D. Todd, Member

Consumer Product Safety Commission  
Dominique Johnson, Member

Department of Agriculture

Clifford P. Rice, Member

Department of Defense

Laurie E. Roszell, Member

Department of the Interior

Barnett A. Rattner, Member

Food and Drug Administration

Kirk Arvidson, Member

Ronald F. Chanderbhan, Alternate

***ITC Staff***

John D. Walker, Director

Carol Savage, Administrative Assistant (NOWCC Employee)

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